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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,920	09/22/2006	Satoshi Tanabe	442P104	5892
42754	7590	08/18/2009		
Nields, Lemack & Frame, LLC			EXAMINER	
176 E. Main Street			BROWN, COURTNEY A	
Suite #5				
Westborough, MA 01581			ART UNIT	PAPER NUMBER
			1616	
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			08/18/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/593,920

**Applicant(s)**

TANABE ET AL.

**Examiner**

COURTNEY BROWN

**Art Unit**

1616

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date 2/12/09
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Acknowledgement of Receipt/Status of Claims***

This Office Action is in response to the amendment filed April 27, 2009. Claims **1-7** are pending in the application. Claims **6** and **7** have been amended. Claims **1-7** are being examined for patentability.

Rejections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

### ***Information Disclosure Statement***

The Information Disclosure Statements (IDS) submitted on February 12, 2009 been considered by the examiner.

The obviousness-type double patenting rejection of claims **1-7** over claims **1, 4-5**, and **7-9** of copending Application No. 10/593,994 in view of James et al. (US Patent 6599941) **is maintained**.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims **1-7** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims **1, 4,5, and 7- 9** of copending Application No. 10/593,994 in view of James et al. (US Patent 6599941). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed subject matter embraces or is embraced by co-pending application 10/593,994.

Copending claims 1,4,5 and 7- 9 and instant claims 1-7 both teach the use of 1-(2,6-dichloro-4- trifluoromethylphenyl)-3-(trifluoromethylthio)indole and 1-(2,6-dichloro-4-trifluoromethylphenyl)-3-(dichlorofluoromethylthio)indole for the control of parasites on companion animals. The difference between the invention of the instant application and

that of copending application 10/593,994 is that the instant invention claims the use of the aforementioned compounds to control acarian parasites as opposed to fleas. James et al. teach that it is well known in the art that pesticides are often useful for controlling both insects and acarians such as mites and ticks (see column 8, lines 8-14). From this extensive overlap of subject matter, one of ordinary skill in the art would recognize that the same product is produced in copending application 10/593,994.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### ***Examiner's Response to Applicant's Remarks***

In the reply filed April 27, 2009, Applicant stated that a terminal disclaimer was filed in co-pending Application 10/593,994 and believes that this filing renders the instant nonstatutory obviousness-type double patenting rejection moot. However, the nonstatutory obviousness-type double patenting rejection must be maintained until claims are in condition for allowance.

The rejection of claims 1-7 under 35 U.S.C. 103(a) as being unpatentable over Hotta et al. (JP 6092935) in view of Wichey-Lakshmanan (Advanced Drug Delivery Reviews) **is maintained**.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

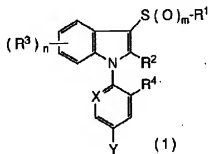
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hotta et al. (JP 6092935) in view of Wichey-Lakshmanan (Advanced Drug Delivery Reviews).**

***Applicant's Invention***

Applicant claims an agent for controlling acarian parasites on mammals characterized by containing an N-substituted indole derivative represented by general formula (I):



wherein X is CH, N or C-halogen atom; Y is a hydrogen atom, a C1-C5 alkyl group optionally substituted by a halogen atom(s), a C2-C5 alkenyl group optionally substituted by a halogen atom(s), a C2-C5 alkynyl group optionally substituted by a halogen atom(s), a C1-C5 alkoxy group optionally substituted by a halogen atom(s), a halogen atom, a cyano group or a nitro group; R<sup>1</sup> is a C1-C5 alkyl group optionally substituted by a halogen atom(s), or a C1-C5 alkoxy group optionally substituted by a halogen atom(s); R<sup>2</sup>, R<sup>3</sup> and R<sup>4</sup> are independently a hydrogen atom, a C1-C5 alkyl group optionally substituted by a halogen atom(s), a C2-C5 alkenyl group optionally substituted by a halogen atom(s), a C2-C5 alkynyl group optionally substituted by a halogen atom(s), a halogen atom, a cyano group, a carboxyl group, a C1-C5

alkoxycarbonyl group optionally substituted by a halogen atom(s), a Cl-U5 acyl group optionally substituted by a halogen atom(s), a nitro group, a cyano group, a thiocyanato group, a Cl-C5 alkoxyl group optionally substituted by a halogen atom(s), or S(O)<sub>k</sub>R<sub>5</sub> wherein k is 0, 1 or 2 and R<sub>5</sub> is a Cl-C5 alkyl group optionally substituted by a halogen atom(s); m is 0, 1 or 2; and n is 1, 2, 3 or 4.

***Determination of the scope and the content of the prior art  
(MPEP 2141.01)***

Hotta et al. teach a composition comprising N-substituted indole derivatives of instant Formula 1 and their use as an insecticide in order to protect man or animal from parasitic hindrance ([0001], claim 1 and 5 of instant application). Hotta teaches the instant N-substituted indoles of formula (I) and their use in an insecticidal composition wherein X is N; Y is a C1-C5 alkyl optionally substituted with a halogen atom; R<sub>1</sub> is a C1-C5 alkyl group; and R<sub>2</sub>, R<sub>3</sub>, and R<sub>4</sub> are independently a hydrogen atom or a C1-C5 alkyl group (see claim 1, General Formula 1 of Hotta et al., claims 1-4 of instant application). Hotta teaches that the indole derivatives can be mixed with a liquid carrier, an emulsifier, a dispersant, or a disintegrator among other excipients (paragraphs [0017]-[0019]).

***Ascertainment of the difference between the prior art and the claims  
(MPEP 2141.02)***

The difference between the invention of the instant application and that of Hotta et al. is that the instant invention claims a shampoo or rinse and liquid drops comprising the N-substituted indole derivatives of instant Formula 1 as opposed to



being silent. For this reason, the teaching of Witchey-Lakshmanan is joined. Witchey-Lakshmanan teach, in a comparison of the advantages and disadvantages of various types of topical products for the control of fleas and ticks, that with the use of shampoos on animals, the active agent has a chance to permeate entirely through the fur onto the skin of said animal (see page 114, Table 1). Witchey-Lakshmanan also teaches that commercially available topical liquids (i.e. spot-ons) are very easy to use and have duration as long as 1 month.

***Finding of prima facie obviousness***

***Rationale and Motivation (MPEP 2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of the cited references to arrive at an agent for controlling acarian parasites on mammals comprising an N-substituted indole derivative represented by general formula (I) and produce the instant invention. Witchey-Lakshmanan teaches that there are advantages through the use of shampoos and liquid drops for the control of parasites on animals. One would have been motivated to make this combination in order to receive the expected benefit of having an agent for controlling acarian parasites on mammals that, when used as a shampoo, provides opportunity for maximum efficacy and when used as liquid drops, provides a low level of transference onto the mammal's surrounding environment (see page 114 of Witchey-Lakshmanan). Thus, in view of *In re Kerkhoven*, 205 USPQ 1069 (C.C.P.A. 1980), it is *prima facie* obvious to combine two or more compositions each of which is taught by

prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in prior art.

All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Therefore, the claimed invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because every element of the invention has been fairly suggested by the cited reference.

***Examiner's Response to Applicant's Remarks***

Applicant's arguments filed on April 27, 2009, with respect to the objection of claims 6 and 7 have been fully considered but are moot in view of Applicant's amendment.

Applicant's arguments filed on April 27, 2007, with respect to the 103 rejection of claims 1-7 over Hotta et al. (JP 6092935) in view of Wichay-Lakshmanan (Advanced Drug Delivery Reviews) have been fully considered but are not persuasive. Applicant argues that Hotta et al. describe the use of an N-substituted indole derivative, which is the same as the derivative of the present invention, in the control of noxious organisms in paddy fields, agricultural fields, and the like. Applicant argues that Hotta et al.

specifically describe only that the indole derivatives were effective in controlling nilaparvata lunge-ns belonging to Hemiptera and plutella xylostella belonging to Lepidoptera which are noxious organisms in agricultural fields, and are totally different from acarians of the present invention, which are insect pests on companion animals such as dogs and cats. Thus, Applicant concedes that it cannot be easily predicted from the teachings of Hotta et al. that the instant indole derivative can effectively control acarians with low toxicity against companion animals. However, the Examiner disagrees because Hotta et al. teach, in paragraph 0001, that the instant compound of formula (I) can be used as a parasitic controlling agent in order to protect a man or an animal from parasitic hindrance. In addition, Hotta et al. also teach, in paragraph 0024, that the instant compound is effective for controlling, in addition to nilaparvata lunge-ns belonging to Hemiptera and plutella xylostella belonging to Lepidoptera, **Aedes aegypti** which is a mosquito that can spread the dengue fever, Chikungunya, yellow fever viruses, and other diseases to humans; **Xenopsylla cheopis** which is the Oriental rat flea, also known as the tropical rat flea and is a parasite of rodents; and **Ctenocephalides canis** which is a dog flea species (see paragraph 0024 of Hotta et al.). Therefore, in view of the teaching of Hotta et al., it would have been obvious to one of ordinary skill in the art to predict that the indole derivatives of instant formula I can effectively control acarina with low toxicity against companion animals.

Applicant asserts that it cannot be easily predicted whether an insecticide that is effective against insects can also control acarians. Respectfully, the Examiner cannot agree. Although the teachings of Watanabe et al. and Morita M et al. show that it

cannot be easily predicted whether an insecticide effective against insects can also control the two spotted spider mite, the teachings of Hotta et al., as previously stated, are not directed towards treating the two spotted spider mite and the instant claims are not directed towards treating the two spotted spider mite and one of ordinary skill in the art would use the parasitic controlling agent of instant formula I in order to protect a man or an animal from parasitic hindrance based upon the teachings of Hotta et al. (see [0001] of Hotta et al.). Thus, the Examiner has established that the claimed agent comprising the N-substituted indole derivatives of instant formula I is prima facie obvious over Hotta et al. in view of Wichey-Lakshmanan.

### **New Rejection(s)**

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims **1-7** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims **1-7** of copending Application No. 12/456,823 in view of James et al. (US Patent 6599941). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed subject matter embraces or is embraced by co-pending application 12/456,823.

Copending claims **1-7** and instant claims **1-7** both teach the use of 1-(2,6-dichloro-4-trifluoromethylphenyl)-3-(trifluoromethylthio)indole and 1-(2,6-dichloro-4-trifluoromethylphenyl)-3-(dichlorofluoromethylthio)indole for the control of parasites on companion animals. The difference between the invention of the instant application and that of copending application 12/456,823 is that the instant invention claims the use of the aforementioned compounds to control acarian parasites as opposed to fleas. James et al. teach that it is well known in the art that pesticides are often useful for controlling both insects and acarians such as mites and ticks (see column 8, lines 8-14). From this extensive overlap of subject matter, one of ordinary skill in the art would recognize that the same product is produced in copending application 12/456,823.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The claims remain rejected.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR Only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electron Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Courtney Brown, whose telephone number is 571-270-3284. The examiner can normally be reached on Monday-Friday from 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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